

## REMARKS

Applicants respectfully request reconsideration of this application in view of the foregoing amendments and the following remarks.

### A. Introductory Remarks

Upon entry of the amendments, claims 15 and 18-25 will remain pending in the application. Claim 15 is currently being amended to indicate that the administered agent is “a precursor of protoporphyrin IX in the biosynthetic pathway for heme.” Exemplary support for the amendment to claim 15 exists in paragraphs 18-21 of the specification. Claims 16-17 are presently being canceled without prejudice or disclaimer. No claims are presently being added.

### B. The Claims Comply with the Enablement Requirement of 35 U.S.C. § 112

Claims 15-19 and 21-25 were rejected for allegedly failing to meet the enablement requirement of 35 U.S.C. § 112, first paragraph. The Office acknowledged that the specification is “enabling for methods of treating malignant skin lesions with 5-aminolevulinic acid (5-ALA),” but stated that it does not enable the use of “any agent which is not itself a photosensitizer but which induces accumulation of protoporphyrin IX in a cellular target.” According to the rejection, the specification does not provide a clear definition for the claim term “agent which is not a photosensitizer but induces the synthesis of protoporphyrin IX *in vivo*,” and Applicants are attempting to limit that term to precursors of protoporphyrin IX without an explicit recitation to that effect.

Without acquiescing in the propriety of the rejection, Applicants have amended the claims to recite that the administered agent is “a precursor of protoporphyrin IX in the biosynthetic pathway for heme.” As described in Applicants’ previous response, those skilled in the art would understand that such precursors are compounds capable of participating, either directly or after an *in vivo* conversion, in the heme biosynthetic pathway and inducing synthesis of protoporphyrin IX.

For an illustration of the heme biosynthetic pathway, Applicants again refer the Examiner to McGilvery et al., Biochemistry: A Fundamental Approach 632-635 (2d ed.

1979) (already of record). This textbook shows the heme biosynthetic pathway and illustrates the role of 5-aminolevulinate. Compounds useful in the invention include those compounds that are involved in the biosynthetic pathway of heme as shown in McGilvery.

Additionally, the present specification discloses at paragraph 0028 that “the usual rate-limiting step in the [heme biosynthetic] process, the synthesis of 5-aminolevulinic acid, can be bypassed by the provision of exogenous ALA, porphobilinogen or other precursor of PpIX.” Those ordinarily skilled in the art would understand an “other precursor” of protoporphyrin IX to include prodrugs of compounds in the heme biosynthetic pathway. Such an “other precursor” would include, for example, an ester of 5-aminolevulinic acid. This is thoroughly explained in Applicants’ previous response.

In view of the foregoing amendments and comments, Applicants respectfully request reconsideration and withdrawal of the enablement rejection.

C. Double Patenting

Claims 15-25 were rejected on the basis of obviousness-type double patenting over claims 1-2 of U.S. Patent No. 5,211,938 and claims 1-7 of U.S. Patent No. 5,069,262. Once the claims in this application are otherwise deemed allowable, Applicants intend to file a terminal disclaimer that will obviate this rejection.

Claims 15-25 were provisionally rejected on the basis of obviousness-type double patenting over claims 1-10 of copending U.S. Patent Application No. 10/663,992, claims 1-20 of copending U.S. Patent Application No. 10/605,826, claims 1-19 of copending U.S. Patent Application No. 09/928,505 and claims 1-15 of copending U.S. Patent Application No. 09/816,329. Because the rejection is merely provisional at this time, Applicants defer any action until an actual rejection is made.

D. Concluding Remarks

This application is now in condition for allowance, and Applicants respectfully request favorable reconsideration of it.

If the Examiner believes that an interview would further advance prosecution, he or she is invited to contact the undersigned attorney by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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